

Proposal for Task Force Consideration at the 2009 Biennial Meeting Interstate Shellfish Sanitation Conference		<input checked="" type="checkbox"/> Growing Area <input type="checkbox"/> Harvesting/Handling/Distribution <input type="checkbox"/> Administrative
Name of Submitter:	US Food and Drug Administration (FDA)	
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Proposal Subject:	Deletions and Additions to Table 1 Action Levels, Tolerances and Guidance Levels for Poisonous or Deleterious Substances in Seafood	
Specific NSSP Guide Reference:	Section IV Guidance Documents Chapter II. Growing Areas .04 Action Levels, Tolerances and Guidance Levels for Poisonous or Deleterious Substances in Seafood	
Text of Proposal/ Requested Action	<p>Delete arsenic, cadmium, chromium, lead, and nickel from Table 1 - Action Levels, Tolerances and Guidance Levels for Poisonous and Deleterious Substances in NSSP Section IV Guidance Documents Chapter II.04.</p> <p>Add the following chemicals and chemotherapeutic drugs and the associated safety level to Table 1 - Action Levels, Tolerances and Guidance Levels for Poisonous and Deleterious Substances in NSSP Guidance Documents Chapter II.04:</p> <p><u>Carbaryl in oysters - 0.25 ppm</u> <u>Endothall and its monomethyl ester in all fish - 0.1 ppm</u> <u>Chloramphenicol in all fish - no residue</u> <u>Clenbuterol in all fish - no residue</u> <u>Diethylstilbestrol (DES) in all fish - no residue</u> <u>Demetridazole in all fish - no residue</u> <u>Iprnidazole and other nitroimidazoles in all fish - no residue</u> <u>Frazolidone and other nitrofurans in all fish - no residue</u> <u>Fluoroquinilones in all fish - no residue</u> <u>Glycopeptides in all fish - no residue</u></p> <p>Delete the less than symbol in front of 20 MU/100 g for Neurotoxic Shellfish Poisoning (NSP) in Table 1 - Action Levels, Tolerances and Guidance Levels for Poisonous and Deleterious Substances in NSSP Guidance Documents Chapter II.-04.</p>	
Public Health Significance:	<p>Acceptable levels established in the FDA guidance documents for each of the five elements to be deleted were intended only as general guidance. Use of these Guidance Documents as a general formula for calculating levels of concern is somewhat subjective based on the particular circumstances under which they are applied, for example, the rate of consumption. Furthermore, in the 14 years since their publication, new scientific data and information has rendered them somewhat obsolete and in need of revision. Until such time as they can be updated with current information and science, FDA toxicologists have determined the safe levels set forth in them for molluscan shellfish are inappropriate.</p> <p>Addition to the NSSP of the two named chemicals and the nine chemotherapeutic drugs is in keeping with establishment of FDA and EPA safety levels for their presence in shellfish meats and with their citation in the FDA Seafood HACCP Fish and Fisheries Products</p>	

	Hazards and Controls Guide.
Cost Information (if available):	None
Action by 2007 Task Force I	Recommended referral of Proposal 07-107 to an appropriate committee as determined by the Conference Chairman.
Action by 2007 General Assembly	Adopted recommendation of 2007 Task Force I.
Action by USFDA	December 20, 2007 Concurred with Conference action.